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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,075	12/17/2003	Perry F. Renshaw	04843/117002	1400

21559 7590 06/20/2006

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	10/740,075	RENSHAW ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

All Participants:

(1) *L. E. Crane*.

(2) *Karen L. Elbing*.

Status of Application: *after non-final rejection*

(3) *J. Cooper McDonald*.

(4) _____.

Date of Interview: *2 May 2006*

Time: *11:30 AM*

Type of Interview:
- ☐ Telephonic
- ☐ Video Conference
- ☒ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☒ No
If Yes, provide a brief description:

Part I.

Rejection(s) discussed:
All of record, 112, 1st, 112, 2nd and obviousness double patenting

Claims discussed:
all of record

Prior art documents discussed:
Renshaw '703.

Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:
See Continuation Sheet

Part III.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.

☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

(Examiner/SPE Signature)

(Applicant/Applicant's Representative Signature – if appropriate)

Continuation of Substance of Interview including description of the general nature of what was discussed:

Examiner and applicant's representatives went through the draft office action (supplied to applicant's representatives by FAX last month and officially mailed May 1, 2006) in page order. Examiner suggested to applicant's representatives that the scope and enablement rejections reflected the difficulties of finding support for the claims in a very limited amount of data obtained with a single test host. Examiner also requested a more readily understandable replacement for, or supplement to, Figure 2 possibly wherein the various test protocols or test results are separately presented to more effectively and clearly illustrate the meanings of the measurements.

Examiner also indicated that the instant case was somewhat reminiscent of Balzarini (Ex parte Balzarini, 21 USPQ 2d 1892 (Bd Pat App & Inter, 1992), the major difference being that instant applicant had some data whereas Balzarini had no test data whatsoever. Applicant's representatives, citing Balzarini, argued that first paragraph rejections required prior art, a view not agreed with by examiner who indicated that scientific reasoning was the actual standard.

Examiner rejected out of hand applicant's representatives suggestion that the scope rejection was a utility rejection, noting that there was some test data (and some prior art) which supports applicant's asserted utility. Examiner also noted that there was no data supporting each and every different alleged active ingredient, noting in particular creatine, a compound which pharmacologically appeared to be an odd compound to be included within the listing of the other active ingredients most of which were nucleosides, nucleotides or compounds known to be agonists of adenosine.

Applicant's representatives indicated that, according to their conversations with applicant Renshaw, addition test data would be difficult to obtain, but that applicant Renshaw did have additional data not yet made of record herein which they hoped would be presentable in declaration(s) to be submitted under 37 C.F.R. §1.132, an effort examiner indicated would be much appreciated and had the potential to give examiner the opportunity to understand applicant's clinical experience in treating sleep/wake disorders with more factual information as supporting disclosure. Examiner recalled that the Office action had noted that the only test subject (Figure 2) appeared to be suffering from multiple dependencies and that it was unclear which dependency or which combination of dependencies was actually being counteracted by applicant's treatment as reported in Figure 2. Examiner suggested that test subjects, humans or lower mammals, might be used to generate data, noting the recent media reports of a study which has clarified the reasons for the cyclic variations in the efficacy of melatonin on the sleep aptitude of humans.

Examiner also noted that the instant claims were generic in some respects and that, depending on the availability of additional data, applicant's might be able to narrow the scope of patient populations and avoid some or all of the cited prior art.

Examiner indicated that the double patenting and the art rejections represented a first take on applying the prior art to the claims. And examiner indicated that he expected to take into consideration all additional data provided by applicant and all amendments to the claims during the process of considering all of applicant's arguments as to the continued applicability of the cited art to the claims.